

K023804

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**IX. 510(k) Summary**

**SUBMITTER:** DePuy AcroMed, Inc.  
325 Paramount Drive  
Raynham, MA 02767

JAN 23 2003

**CONTACT PERSON:** Lisa A. Gilman

**DATE PREPARED:** August 2, 2002

**CLASSIFICATION NAME:** Appliance, Fixation, Spinal Interlaminar  
Orthosis, Spinal Pedicle Fixation

**PROPRIETARY NAME:** Moss Miami Spinal System Pin Nut

**PREDICATE DEVICES:** Moss Miami Spinal System Titanium Pin Nut  
(K010742)

**INTENDED USE:** When used as a posterior, noncervical hook, and/or sacral/ilic screw fixation system, or as an anterior, thoracic/lumbar screw fixation system, the Moss Miami Spinal System is intended to treat scoliosis, kyphosis and lordosis, fracture, loss of stability due to tumor, spinal stenosis, spondylolisthesis, a previously failed fusion surgery or degenerative disc disease (i.e., discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies).

When used as a pedicle screw fixation system of the noncervical spine in skeletally mature patients, the Moss Miami Spinal System is indicated for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

## Moss Miami Spinal System Pin Nut

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The Moss Miami Spinal System is also indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) at the L5 – S1 vertebral joint, having fusions with autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation are L3 – S1), and for whom the device system is intended to be removed after solid fusion is attained.

### MATERIALS:

Manufactured from ASTM F-136 implant grade titanium alloy and ASTM F-138 implant grade stainless steel.

### PERFORMANCE

#### DATA:

Data were submitted to characterize the Moss Miami Spinal System Pin Nut.

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 23 2003

Ms. Lisa Gilman  
Regulatory Affairs Associate  
DePuy AcroMed, Inc.  
325 Paramount Drive  
Raynham, Massachusetts 02767-0350

Re: K023804

Trade/Device Name: Moss Miami Spinal System Pin Nut  
Regulation Number: 21 CFR 888.3050, 21 CFR 888.3070  
Regulation Name: Spinal interlaminar fixation orthosis; Spondylolisthesis spinal fixation device system; Pedicle screw spinal system  
Regulatory Class: Class II  
Product Code: KWP, MNH, MNI  
Dated: January 6, 2003  
Received: January 7, 2003

Dear Ms. Gilman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

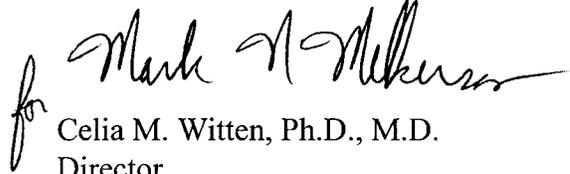
Page 2 - Ms. Lisa Gilman

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

for Mark A. Melkus

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

III. Indications for Use

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510(k) Number (if known): K023804

Device Name: Moss Miami Spinal System Pin Nut

Indications For Use:

When used as a posterior, noncervical hook, and/or sacral/ilic screw fixation system, or as an anterior, thoracic/lumbar screw fixation system, the Moss Miami Spinal System is intended to treat scoliosis, kyphosis and lordosis, fracture, loss of stability due to tumor, spinal stenosis, spondylolisthesis, a previously failed fusion surgery or degenerative disc disease (i.e., discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies).

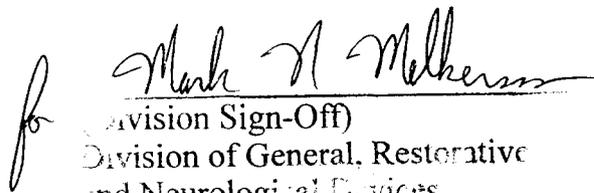
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(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: \_\_\_\_\_ OR Over-The-Counter Use: \_\_\_\_\_  
(Per 21 CFR 801.109)

  
Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K023804